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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/311,996	05/14/1999	EUGENI A. VAISBERG	19681-4	1991

22434 7590 03/10/2003

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EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/10/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/311,996

Applicant(s)

VAISBERG ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002 and 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-57,60,61 and 63-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-57,60,61 and 63-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13, 23. 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. This application has been reassigned to a new examiner.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 January 2003 has been entered.

Information Disclosure Statement

3. The reference U.S. Provisional Application No. 60/127339 has now been indicated as considered on the Form PTO 1449 filed 04 January 2002 as the cited application is properly cited under 37 CFR 1.98.

Specification

4. The appendix has been inserted into the specification as pages 47-65, and original pages 47-53 have been renumbered as pages 66-72
5. The disclosure is objected to because of the following informalities: The tables appearing on pages 47-65 are objected to as not in compliance with the letter size requirements of 37 CFR 1.58. It is suggested that the applicants either submit the tables as drawings under 37 CFR 1.84(d) or delete pages 47-65 of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The rejection of claims 49-61 under 35 U.S.C. § 112, first paragraph for lack of written description in the Office action mailed 16 July 2002 is withdrawn in view of the amendment filed 23 December 2002.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-55, and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 49-55 and 66 are indefinite because it is not clear whether the computer readable storage medium comprises the computer program. The rejection would be overcome by amending claim 49 to explicitly state that the computer readable medium comprises the computer program.

Claim 66 is indefinite for recitation of the phrases “applying an electroporation” and “applying a gene knockout, applying a gene overexpression, applying a gene mutation, applying a cell fusion” because the recitation concerns methods rather than compounds. The rejection would be overcome by amending claim 66 to recite “an electroporation” and “a gene knockout, a gene overexpression, a gene mutation, a cell fusion.”

For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 49-57, 60, 61, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over BIODX, Weaver et al., Pauwels et al., and Weinstein or BIODX, Singhvi et al. Pauwels et al., and Weinstein further in view of Sundblad et al. for reasons of record in the Office action mailed 16 July 2002.

Claims 49 and 66 rejected under 35 U.S.C. 103(a) as being unpatentable over BIODX, Weaver et al., Pauwels et al., and Weinstein or BIODX, Singhvi et al. Pauwels et al., and

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Weinstein further in view of Sundblad et al. as applied to claims 49-57, 60, 61, and 63-65 above, and further in view of Rojanasakul.

Claim 66 is drawn to the method of claim 49 further limited to a manipulation of treatment with antisense polynucleotides.

BIODX, Weaver et al., Pauwels et al., and Weinstein or BIODX, Singhvi et al. Pauwels et al., and Weinstein further in view of Sundblad et al. as applied to claims 49-57, 60, 61, and 63-65 above does not show treatment with antisense polynucleotides.

Rojanasakul shows in the abstract and throughout that antisense polynucleotides are useful to inhibit gene expression, and may prove useful for therapeutic applications.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the research methodology method of analysis of cellular manipulations of BIODX, Weaver et al., Pauwels et al., and Weinstein or BIODX, Singhvi et al. Pauwels et al., and Weinstein further in view of Sundblad et al. as applied to claims 49-57, 60, 61, and 63-65 above by use of the antisense polynucleotides of Rojanasakul because Rojanasakul shows that antisense polynucleotides show promise for use in therapy.

10. Applicant's arguments filed 23 December 2002 have been fully considered but they are not persuasive. The applicants state that BIODX does not show combination of descriptors, however Pauwels et al. shows on page 107 a combined analysis of 15 parameters. The applicants state that the cited references do not show principal component analysis of cell image data, however Pauwels et al. shows such analysis in figures 3 and 6.

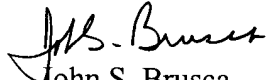
Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.


John S. Brusca
Primary Examiner
Art Unit 1631

jsb
March 7, 2003